Kline, Cliff

From: Free, Donna
Sent: Monday, January 03, 2005 3:26 PM
To: 'Allen, Samie Niver'
Cc: Michael, Maher; Kline, Cliff
Subject: P030053A5 - Core Study

Hi Samie,

Based on our discussion earlier today, we have modified Tables 9.1(Reoperative Report: Type of Additional Surgical Procedures) and 9.2 (Reoperative Report: Primary Reason for Reoperation) for ease of review and clarity. The attached tables supersede the tables previously sent in Mentor's email dated 12/20/04.

Regards,

Donna

Core Gel Study of the Safety and Effectiveness of the Mentor Round Gel Filled Mammary Prosthesis
in Patients Who Are Undergoing Primary Breast Augmentation, Primary Breast Reconstruction or Revision

Table 9.1

REOPERATIVE REPORT: TYPE OF ADDITIONAL SURGICAL PROCEDURES - FDA Item 10
AUGMENTATION PATIENTS

Time Period. 0 - 12 Months

Type of Additional Surgical Proccedure	No. of Additional Surgical Procedures n(%)
Biopsy	2 (2.5)
Capsulectomy	18 (22.8)
Capsulorrhaphy	4 (5.1)
Capsulotomy	8 (10.1)
Implant Pocket Revision	0 (0.0)
Implant Removal (With Replacement)	14 (17.7)
Implant Removal (Without Replacement)	8 (10.1)
Implant Reposition	2 (2.5)
Incision and Drainage	11 (13.9)
Mastopexy	0 (0.0)
Nipple Related Procedure (unplanned)	1 (1.3)
Revision Of Wound Closure	3 (3.8)
Scar Revision	5 (6.3)
Skin Adjustment	3 (3.8)
Other	0 (0.0)
Create Inframmary Fold	0 (0.0)
Excision Of Skin Lesion	0 (0.0)
Removal Of Nodule On Chest Wall	0 (0.0)

Program Name: Q.\MENTOR\COREGEL\3YEAR\TABLES\T09_1.SAS Creation Date, Time. 03JAN05 14:20

Note 1: Excludes planned second stage surgeries and reoperations for which the only reason for reoperation was staged reconstruction.
Note 2: Within capsulotomies, there were 6 closed capsulotomy reoperations involving 3 implants and 2 patients in revision patients.
Note 3: Percentages are based upon Total Assessed with Additional Surgical Procedures.
Note 4. There were 53 patients who had 56 reoperations and 79 additional surgical procedures.

Core Gel Study of the Safety and Effectiveness of the Mentor Round Gel-Filled Mammary Prosthesis
in Patients Who Are Undergoing Primary Breast Augmentation, Primary Breast Reconstruction or Revision

Table 9.1

REOPERATIVE REPORT. TYPE OF ADDITIONAL SURGICAL PROCEDURES - FDA Item 10
AUGMENTATION PATIENTS

Time Period: 0 - 24 Months

Type of Additional Surgical Proccedure	No. of Additional Surgical Procedures n(%)
Biopsy	4 (3.0)
Capsulectomy	31 (23.5)
Capsulorrhaphy	4 (3.0)
Capsulotomy	14 (10.6)
Implant Pocket Revision	2 (1.5)
Implant Removal (With Replacement)	20 (15.2)
Implant Removal (Without Replacement)	14 (10.6)
Implant Reposition	4 (3.0)
Incision and Drainage	12 (9.1)
Mastopexy	2 (1.5)
Nipple Related Procedure (unplanned)	1 (0.8)
Revision Of Wound Closure	3 (2.3)
Scar Revision	15 (11.4)
Skin Adjustment	5 (3.8)
Other	1 (0.8)
Create Inframmary Fold	0 (0.0)
Excise Breast Mass	1 (0.8)
Excision Of Skin Lesion	0 (0.0)
Exploration Right Breast With Evacuation Of Hematoma	0 (0.0)
Flap Coverage Of Expander	0 (0.0)
Removal Of Nodule On Chest Wall	0 (0.0)
Revision Of Breast / External To Pocket	0 (0.0)

Note 1: Excludes planned second stage surgeries and reoperations for which the only reason for reoperation was staged reconstruction.
Note 2: Within capsulotomies, there were 6 closed capsulotomy reoperations involving 3 implants and 2 patients in revision patients.
Note 3: Percentages are based upon Total Assessed with Additional Surgical Procedures.
Note 4: There were 68 patients who had 83 reoperations and 132 additional surgical procedures.

Core Gel Study of the Safety and Effectiveness of the Mentor Round Gel-Filled Mammary Prosthesis
in Patients Who Are Undergoing Primary Breast Augmentation, Primary Breast Reconstruction or Revision

Table 9.1

REOPERATIVE REPORT: TYPE OF ADDITIONAL SURGICAL PROCEDURES - FDA Item 10
AUGMENTATION PATIENTS

Time Period: 0 - 36 Months

Type of Additional Surgical Proccedure	No. of Additional Surgical Procedures n(%)
Biopsy	4 (2.5)
Capsulectomy	36 (22.5)
Capsulorrhaphy	4 (2.5)
Capsulotomy	17 (10.6)
Implant Pocket Revision	2 (1.3)
Implant Removal (With Replacement)	24 (15.0)
Implant Removal (Without Replacement)	21 (13.1)
Implant Reposition	4 (2.5)
Incision and Drainage	12 (7.5)
Mastopexy	4 (2.5)
Nipple Related Procedure (unplanned)	1 (0.6)
Revision Of Wound Closure	3 (1.9)
Scar Revision	18 (11.3)
Skin Adjustment	8 (5.0)
Other	2 (1.3)
Breast Mass Excision Dx: Fibroadenoma	0 (0.0)
Create Inframmary Fold	0 (0.0)
Excise Breast Mass	2 (1.3)
Excision Of Skin Lesion	0 (0.0)
Exploration Right Breast With Evacuation Of Hematoma	0 (0.0)
Flap Coverage Of Expander	0 (0.0)
Needle Aspiration	0 (0.0)
Open Incision To Rule Out Implant Rupture	0 (0.0)
Removal Of Nodule On Chest Wall	0 (0.0)

Program Name: Q.\MENTOR\COREGEL\3YEAR\TABLES\T09_1.SAS Creation Date, Time: 03JAN05 14:20

Note 1: Excludes planned second stage surgeries and reoperations for which the only reason for reoperation was staged reconstruction.
Note 2: Within capsulotomies, there were 6 closed capsulotomy reoperations involving 3 implants and 2 patients in revision patients.
Note 3: Percentages are based upon Total Assessed with Additional Surgical Procedures.
Note 4: There were 79 patients who had 98 reoperations and 160 additional surgical procedures.

Core Gel Study of the Safety and Effectiveness of the Mentor Round Gel-Filled Mammary Prosthesis
in Patients Who Are Undergoing Primary Breast Augmentation, Primary Breast Reconstruction or Revision

Table 9.1

REOPERATIVE REPORT: TYPE OF ADDITIONAL SURGICAL PROCEDURES - FDA Item 10
AUGMENTATION PATIENTS

Time Period: 0 - 36 Months

Type of Additional Surgical Proccedure	No. of Additional Surgical Procedures n(%)
Revision Of Breast / External To Pocket	0 (0.0)

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Note 1: Excludes planned second stage surgeries and reoperations for which the only reason for reoperation was staged reconstruction.
Note 2: Within capsulotomies, there were 6 closed capsulotomy reoperations involving 3 implants and 2 patients in revision patients.
Note 3: Percentages are based upon Total Assessed with Additional Surgical Procedures.
Note 4. There were 79 patients who had 98 reoperations and 160 additional surgical procedures.

Core Gel Study of the Safety and Effectiveness of the Mentor Round Gel-Filled Mammary Prosthesis
in Patients Who Are Undergoing Primary Breast Augmentation, Primary Breast Reconstruction or Revision

Table 9.1

REOPERATIVE REPORT: TYPE OF ADDITIONAL SURGICAL PROCEDURES - FDA Item 10
RECONSTRUCTION PATIENTS

Time Period: 0 - 12 Months

Type of Additional Surgical Proccedure	No. of Additional Surgical Procedures n(%)
Biopsy	8 (8.1)
Capsulectomy	7 (7.1)
Capsulorrhaphy	2 (2.0)
Capsulotomy	13 (13.1)
Implant Pocket Revision	4 (4.0)
Implant Removal (With Replacement)	17 (17.2)
Implant Removal (Without Replacement)	9 (9.1)
Implant Reposition	12 (12.1)
Incision and Drainage	3 (3.0)
Mastopexy	1 (1.0)
Nipple Related Procedure (unplanned)	2 (2.0)
Revision Of Wound Closure	1 (1.0)
Scar Revision	4 (4.0)
Skin Adjustment	12 (12.1)
Other	4 (4.0)
Create Inframmary Fold	2 (2.0)
Excision Of Skin Lesion	0 (0.0)
Removal Of Nodule On Chest Wall	2 (2.0)

Note 1: Excludes planned second stage surgeries and reoperations for which the only reason for reoperation was staged reconstruction.
Note 2: Within capsulotomies, there were 6 closed capsulotomy reoperations involving 3 implants and 2 patients in revision patients.
Note 3: Percentages are based upon Total Assessed with Additional Surgical Procedures.
Note 4. There were 48 patients who had 55 reoperations and 99 additional surgical procedures.

Core Gel Study of the Safety and Effectiveness of the Mentor Round Gel-Filled Mammary Prosthesis
in Patients Who Are Undergoing Primary Breast Augmentation, Primary Breast Reconstruction or Revision

Table 9.1

REOPERATIVE REPORT: TYPE OF ADDITIONAL SURGICAL PROCEDURES - FDA Item 10
RECONSTRUCTION PATIENTS

Time Period: 0 - 24 Months

Type of Additional Surgical Proccedure	No. of Additional Surgical Procedures n(%)
Biopsy	10 (7.6)
Capsulectomy	10 (7.6)
Capsulorrhaphy	2 (1.5)
Capsulotomy	14 (10.6)
Implant Pocket Revision	6 (4.5)
Implant Removal (With Replacement)	23 (17.4)
Implant Removal (Without Replacement)	13 (9.8)
Implant Reposition	17 (12.9)
Incision and Drainage	3 (2.3)
Mastopexy	3 (2.3)
Nipple Related Procedure (unplanned)	2 (1.5)
Revision Of Wound Closure	1 (0.8)
Scar Revision	7 (5.3)
Skin Adjustment	14 (10.6)
Other	7 (5.3)
Create Inframmary Fold	2 (1.5)
Excise Breast Mass	0 (0.0)
Excision Of Skin Lesion	0 (0.0)
Exploration Right Breast With Evacuation Of Hematoma	0 (0.0)
Flap Coverage Of Expander	1 (0.8)
Removal Of Nodule On Chest Wall	2 (1.5)
Revision Of Breast / External To Pocket	2 (1.5)

Note 1: Excludes planned second stage surgeries and reoperations for which the only reason for reoperation was staged reconstruction.
Note 2: Within capsulotomies, there were 6 closed capsulotomy reoperations involving 3 implants and 2 patients in revision patients.
Note 3: Percentages are based upon Total Assessed with Additional Surgical Procedures.
Note 4. There were 63 patients who had 73 reoperations and 132 additional surgical procedures.

Core Gel Study of the Safety and Effectiveness of the Mentor Round Gel-Filled Mammary Prosthesis
in Patients Who Are Undergoing Primary Breast Augmentation, Primary Breast Reconstruction or Revision

Table 9.1

REOPERATIVE REPORT: TYPE OF ADDITIONAL SURGICAL PROCEDURES - FDA Item 10
RECONSTRUCTION PATIENTS

Time Period: 0 - 36 Months

Type of Additional Surgical Proccedure	No. of Additional Surgical Procedures n(%)
Biopsy	10 (7.2)
Capsulectomy	10 (7.2)
Capsulorrhaphy	2 (1.4)
Capsulotomy	14 (10.1)
Implant Pocket Revision	6 (4.3)
Implant Removal (With Replacement)	23 (16.5)
Implant Removal (Without Replacement)	17 (12.2)
Implant Reposition	17 (12.2)
Incision and Drainage	4 (2.9)
Mastopexy	4 (2.9)
Nipple Related Procedure (unplanned)	2 (1.4)
Revision Of Wound Closure	1 (0.7)
Scar Revision	7 (5.0)
Skin Adjustment	14 (10.1)
Other	8 (5.8)
Breast Mass Excision Dx: Fibroadenoma	1 (0.7)
Create Inframmary Fold	2 (1.4)
Excise Breast Mass	0 (0.0)
Excision Of Skin Lesion	0 (0.0)
Exploration Right Breast With Evacuation Of Hematoma	0 (0.0)
Flap Coverage Of Expander	1 (0.7)
Needle Aspiration	0 (0.0)
Open Incision To Rule Out Implant Rupture	0 (0.0)
Removal Of Nodule On Chest Wall	2 (1.4)

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Note 1: Excludes planned second stage surgeries and reoperations for which the only reason for reoperation was staged reconstruction.
Note 2: Within capsulotomies, there were 6 closed capsulotomy reoperations involving 3 implants and 2 patients in revision patients.
Note 3: Percentages are based upon Total Assessed with Additional Surgical Procedures.
Note 4: There were 64 patients who had 78 reoperations and 139 additional surgical procedures.

Core Gel Study of the Safety and Effectiveness of the Mentor Round Gel-Filled Mammary Prosthesis
in Patients Who Are Undergoing Primary Breast Augmentation, Primary Breast Reconstruction or Revision

Table 9.1

REOPERATIVE REPORT: TYPE OF ADDITIONAL SURGICAL PROCEDURES - FDA Item 10
RECONSTRUCTION PATIENTS

Time Period: 0 - 36 Months

Type of Additional Surgical Proccedure	No. of Additional Surgical Procedures n(%)
Revision Of Breast / External To Pocket	2 (1.4)

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Note 1: Excludes planned second stage surgeries and reoperations for which the only reason for reoperation was staged reconstruction.
Note 2: Within capsulotomies, there were 6 closed capsulotomy reoperations involving 3 implants and 2 patients in revision patients.
Note 3: Percentages are based upon Total Assessed with Additional Surgical Procedures.
Note 4: There were 64 patients who had 78 reoperations and 139 additional surgical procedures.

Core Gel Study of the Safety and Effectiveness of the Mentor Round Gel-Filled Mammary Prosthesis
in Patients Who Are Undergoing Primary Breast Augmentation, Primary Breast Reconstruction or Revision

Table 9.1

REOPERATIVE REPORT: TYPE OF ADDITIONAL SURGICAL PROCEDURES - FDA Item 10
REVISION PATIENTS

Time Period: 0 - 12 Months

Type of Additional Surgical Proccedure	No. of Additional Surgical Procedures n(%)
Biopsy	6 (6.9)
Capsulectomy	12 (13.8)
Capsulorrhaphy	4 (4.6)
Capsulotomy	14 (16.1)
Implant Pocket Revision	0 (0.0)
Implant Removal (With Replacement)	12 (13.8)
Implant Removal (Without Replacement)	6 (6.9)
Implant Reposition	4 (4.6)
Incision and Drainage	7 (8.0)
Mastopexy	4 (4.6)
Nipple Related Procedure (unplanned)	0 (0.0)
Revision Of Wound Closure	2 (2.3)
Scar Revision	5 (5.7)
Skin Adjustment	9 (10.3)
Other	2 (2.3)
Create Inframmary Fold	0 (0.0)
Excision Of Skin Lesion	2 (2.3)
Removal Of Nodule On Chest Wall	0 (0.0)

Note 1: Excludes planned second stage surgeries and reoperations for which the only reason for reoperation was staged reconstruction.
Note 2: Within capsulotomies, there were 6 closed capsulotomy reoperations involving 3 implants and 2 patients in revision patients.
Note 3: Percentages are based upon Total Assessed with Additional Surgical Procedures.
Note 4: There were 32 patients who had 45 reoperations and 87 additional surgical procedures.

Core Gel Study of the Safety and Effectiveness of the Mentor Round Gel-Filled Mammary Prosthesis
in Patients Who Are Undergoing Primary Breast Augmentation, Primary Breast Reconstruction or Revision

Table 9.1

REOPERATIVE REPORT: TYPE OF ADDITIONAL SURGICAL PROCEDURES - FDA Item 10
REVISION PATIENTS

Time Period. 0 - 24 Months

Type of Additional Surgical Proccedure	No. of Additional Surgical Procedures n(%)
Biopsy	8 (6.7)
Capsulectomy	14 (11.8)
Capsulorrhaphy	6 (5.0)
Capsulotomy	16 (13.4)
Implant Pocket Revision	0 (0.0)
Implant Removal (With Replacement)	18 (15.1)
Implant Removal (Without Replacement)	13 (10.9)
Implant Reposition	8 (6.7)
Incision and Drainage	7 (5.9)
Mastopexy	4 (3.4)
Nipple Related Procedure (unplanned)	0 (0.0)
Revision Of Wound Closure	2 (1.7)
Scar Revision	8 (6.7)
Skin Adjustment	12 (10.1)
Other	3 (2.5)
Create Inframmary Fold	0 (0.0)
Excise Breast Mass	0 (0.0)
Excision Of Skin Lesion	2 (1.7)
Exploration Right Breast With Evacuation Of Hematoma	1 (0.8)
Flap Coverage Of Expander	0 (0.0)
Removal Of Nodule On Chest Wall	0 (0.0)
Revision Of Breast / External To Pocket	0 (0.0)

Note 1: Excludes planned second stage surgeries and reoperations for which the only reason for reoperation was staged reconstruction.
Note 2: Within capsulotomies, there were 6 closed capsulotomy reoperations involving 3 implants and 2 patients in revision patients.
Note 3: Percentages are based upon Total Assessed with Additional Surgical Procedures.
Note 4: There were 43 patients who had 62 reoperations and 119 additional surgical procedures.

Core Gel Study of the Safety and Effectiveness of the Mentor Round Gel-Filled Mammary Prosthesis
in Patients Who Are Undergoing Primary Breast Augmentation, Primary Breast Reconstruction or Revision

Table 9 1

REOPERATIVE REPORT. TYPE OF ADDITIONAL SURGICAL PROCEDURES - FDA Item 10
REVISION PATIENTS

Time Period: 0 - 36 Months

Type of Additional Surgical Proccedure	No. of Additional Surgical Procedures n(%)
Biopsy	10 (7.1)
Capsulectomy	18 (12.8)
Capsulorrhaphy	6 (4.3)
Capsulotomy	17 (12.1)
Implant Pocket Revision	0 (0.0)
Implant Removal (With Replacement)	21 (14.9)
Implant Removal (Without Replacement)	18 (12.8)
Implant Reposition	10 (7.1)
Incision and Drainage	7 (5.0)
Mastopexy	5 (3.5)
Nipple Related Procedure (unplanned)	1 (0.7)
Revision Of Wound Closure	2 (1.4)
Scar Revision	9 (6.4)
Skin Adjustment	12 (8.5)
Other	5 (3.5)
Breast Mass Excision Dx: Fibroadenoma	0 (0.0)
Create Inframmary Fold	0 (0.0)
Excise Breast Mass	0 (0.0)
Excision Of Skin Lesion	2 (1.4)
Exploration Right Breast With Evacuation Of Hematoma	1 (0.7)
Flap Coverage Of Expander	0 (0.0)
Needle Aspiration	1 (0.7)
Open Incision To Rule Out Implant Rupture	1 (0.7)
Removal Of Nodule On Chest Wall	0 (0.0)

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Note 1: Excludes planned second stage surgeries and reoperations for which the only reason for reoperation was staged reconstruction.
Note 2: Within capsulotomies, there were 6 closed capsulotomy reoperations involving 3 implants and 2 patients in revision patients.
Note 3: Percentages are based upon Total Assessed with Additional Surgical Procedures.
Note 4: There were 51 patients who had 71 reoperations and 141 additional surgical procedures.

Core Gel Study of the Safety and Effectiveness of the Mentor Round Gel-Filled Mammary Prosthesis
in Patients Who Are Undergoing Primary Breast Augmentation, Primary Breast Reconstruction or Revision

Table 9.1

REOPERATIVE REPORT: TYPE OF ADDITIONAL SURGICAL PROCEDURES - FDA Item 10
REVISION PATIENTS

Time Period: 0 - 36 Months

Type of Additional Surgical Proccedure	No. of Additional Surgical Procedures n(%)
Revision Of Breast / External To Pocket	0 (0.0)

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Note 1: Excludes planned second stage surgeries and reoperations for which the only reason for reoperation was staged reconstruction.
Note 2: Within capsulotomies, there were 6 closed capsulotomy reoperations involving 3 implants and 2 patients in revision patients.
Note 3: Percentages are based upon Total Assessed with Additional Surgical Procedures.
Note 4: There were 51 patients who had 71 reoperations and 141 additional surgical procedures.

Core Gel Study of the Safety and Effectiveness of the Mentor Round Gel-Filled Mammary Prosthesis
in Patients Who Are Undergoing Primary Breast Augmentation, Primary Breast Reconstruction or Revision

Table 9.1

REOPERATIVE REPORT: TYPE OF ADDITIONAL SURGICAL PROCEDURES - FDA Item 10
OVERALL PATIENTS

Time Period: 0 - 12 Months

Type of Additional Surgical Proccedure	No. of Additional Surgical Procedures n(%)
Biopsy	16 (6.0)
Capsulectomy	37 (14.0)
Capsulorrhaphy	10 (3.8)
Capsulotomy	35 (13.2)
Implant Pocket Revision	4 (1.5)
Implant Removal (With Replacement)	43 (16.2)
Implant Removal (Without Replacement)	23 (8.7)
Implant Reposition	18 (6.8)
Incision and Drainage	21 (7.9)
Mastopexy	5 (1.9)
Nipple Related Procedure (unplanned)	3 (1.1)
Revision Of Wound Closure	6 (2.3)
Scar Revision	14 (5.3)
Skin Adjustment	24 (9.1)
Other	6 (2.3)
Create Inframmary Fold	2 (0.8)
Excision Of Skin Lesion	2 (0.8)
Removal Of Nodule On Chest Wall	2 (0.8)

Note 1. Excludes planned second stage surgeries and reoperations for which the only reason for reoperation was staged reconstruction.
Note 2: Within capsulotomies, there were 6 closed capsulotomy reoperations involving 3 implants and 2 patients in revision patients.
Note 3: Percentages are based upon Total Assessed with Additional Surgical Procedures.
Note 4: There were 133 patients who had 156 reoperations and 265 additional surgical procedures.

Core Gel Study of the Safety and Effectiveness of the Mentor Round Gel-Filled Mammary Prosthesis
in Patients Who Are Undergoing Primary Breast Augmentation, Primary Breast Reconstruction or Revision

Table 9.1

REOPERATIVE REPORT: TYPE OF ADDITIONAL SURGICAL PROCEDURES - FDA Item 10
OVERALL PATIENTS

Time Period: 0 - 24 Months

Type of Additional Surgical Proccedure	No. of Additional Surgical Procedures n(%)
Biopsy	22 (5.7)
Capsulectomy	55 (14.4)
Capsulorrhaphy	12 (3.1)
Capsulotomy	44 (11.5)
Implant Pocket Revision	8 (2.1)
Implant Removal (With Replacement)	61 (15.9)
Implant Removal (Without Replacement)	40 (10.4)
Implant Reposition	29 (7.6)
Incision and Drainage	22 (5.7)
Mastopexy	9 (2.3)
Nipple Related Procedure (unplanned)	3 (0.8)
Revision Of Wound Closure	6 (1.6)
Scar Revision	30 (7.8)
Skin Adjustment	31 (8.1)
Other	11 (2.9)
Create Inframmary Fold	2 (0.5)
Excise Breast Mass	1 (0.3)
Excision Of Skin Lesion	2 (0.5)
Exploration Right Breast With Evacuation Of Hematoma	1 (0.3)
Flap Coverage Of Expander	1 (0.3)
Removal Of Nodule On Chest Wall	2 (0.5)
Revision Of Breast / External To Pocket	2 (0.5)

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Note 1: Excludes planned second stage surgeries and reoperations for which the only reason for reoperation was staged reconstruction
Note 2: Within capsulotomies, there were 6 closed capsulotomy reoperations involving 3 implants and 2 patients in revision patients.
Note 3: Percentages are based upon Total Assessed with Additional Surgical Procedures.
Note 4: There were 174 patients who had 218 reoperations and 383 additional surgical procedures.

Core Gel Study of the Safety and Effectiveness of the Mentor Round Gel-Filled Mammary Prosthesis
in Patients Who Are Undergoing Primary Breast Augmentation, Primary Breast Reconstruction or Revision

Table 9.1

REOPERATIVE REPORT: TYPE OF ADDITIONAL SURGICAL PROCEDURES - FDA Item 10
OVERALL PATIENTS

Time Period: 0 - 36 Months

Type of Additional Surgical Proccedure	No. of Additional Surgical Procedures n(%)
Biopsy	24 (5.5)
Capsulectomy	64 (14.5)
Capsulorrhaphy	12 (2.7)
Capsulotomy	48 (10.9)
Implant Pocket Revision	8 (1.8)
Implant Removal (With Replacement)	68 (15.5)
Implant Removal (Without Replacement)	56 (12.7)
Implant Reposition	31 (7.0)
Incision and Drainage	23 (5.2)
Mastopexy	13 (3.0)
Nipple Related Procedure (unplanned)	4 (0.9)
Revision Of Wound Closure	6 (1.4)
Scar Revision	34 (7.7)
Skin Adjustment	34 (7.7)
Other	15 (3.4)
Breast Mass Excision Dx: Fibroadenoma	1 (0.2)
Create Inframmary Fold	2 (0.5)
Excise Breast Mass	2 (0.5)
Excision Of Skin Lesion	2 (0.5)
Exploration Right Breast With Evacuation Of Hematoma	1 (0.2)
Flap Coverage Of Expander	1 (0.2)
Needle Aspiration	1 (0.2)
Open Incision To Rule Out Implant Rupture	1 (0.2)
Removal Of Nodule On Chest Wall	2 (0.5)

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Note 1: Excludes planned second stage surgeries and reoperations for which the only reason for reoperation was staged reconstruction.
Note 2: Within capsulotomies, there were 6 closed capsulotomy reoperations involving 3 implants and 2 patients in revision patients.
Note 3: Percentages are based upon Total Assessed with Additional Surgical Procedures.
Note 4: There were 194 patients who had 247 reoperations and 440 additional surgical procedures.

Core Gel Study of the Safety and Effectiveness of the Mentor Round Gel-Filled Mammary Prosthesis
in Patients Who Are Undergoing Primary Breast Augmentation, Primary Breast Reconstruction or Revision

Table 9.1

REOPERATIVE REPORT: TYPE OF ADDITIONAL SURGICAL PROCEDURES - FDA Item 10
OVERALL PATIENTS

Time Period: 0 - 36 Months

Type of Additional Surgical Proccedure	No. of Additional Surgical Procedures n(%)
Revision Of Breast / External To Pocket	2 (0.5)

Program Name: Q:\MENTOR\COREGEL\3YEAR\TABLES\T09_1.SAS Creation Date, Time: 03JAN05 14:20

Note 1: Excludes planned second stage surgeries and reoperations for which the only reason for reoperation was staged reconstruction.
Note 2: Within capsulotomies, there were 6 closed capsulotomy reoperations involving 3 implants and 2 patients in revision patients.
Note 3: Percentages are based upon Total Assessed with Additional Surgical Procedures.
Note 4: There were 194 patients who had 247 reoperations and 440 additional surgical procedures.

Core Gel Study of the Safety and Effectiveness of the Mentor Round Gel-Filled Mammary Prosthesis
in Patients Who Are Undergoing Primary Breast Augmentation, Primary Breast Reconstruction or Revision

Table 9.2

REOPERATIVE REPORT: PRIMARY REASON FOR REOPERATION - FDA Item 11
AUGMENTATION PATIENTS

Time Period. 0 - 12 Months

Primary Reason for Reoperation	No. of Reoperation n(%)
ASYMMETRY	5 (8.9)
BREAST MASS	1 (1.8)
BREAST PAIN	0 (0.0)
CAPSULAR CONTRACTURE III/IV	22 (39.3)
DELAYED WOUND HEALING	1 (1.8)
EXTRUSION	1 (1.8)
HEMATOMA	10 (17.9)
HYPERTROPHIC SCARRING	4 (7.1)
IMPLANT MALPOSITION/DISPLACEMENT	1 (1.8)
INFECTION	3 (5.4)
IRRITATION/INFLAMMATION	0 (0.0)
NIPPLE RELATED (UNPLANNED)	0 (0.0)
PATIENT REQUEST	19 (33.9)
PTOSIS	2 (3.6)
SEROMA	1 (1.8)
WRINKLING	1 (1.8)
OTHER	2 (3.6)
BREAST / SKIN LESIONS	0 (0.0)
EXTRA SKIN BUMP	0 (0.0)
GRANULOMA	0 (0.0)
MUSCLE SPASM	0 (0.0)
POCKET TEAR	0 (0.0)

Program Name: Q:\MENTOR\COREGEL\3YEAR\TABLES\T09_2.SAS

Creation Date, Time: 03JAN05 14:21

Note 1: Excludes planned second stage surgeries and reoperations for which the only reason for reoperation was staged reconstruction.
Note 2: Only the primary reason was to be recorded by the physician on a per-breast and per-operation basis. Patients having multiple operations, including operations on both breasts on the same date, will therefore be counted under multiple primary reasons. Consequently, percentages calculated may exceed 100%.
Note 3: Percentages are based upon the number of reoperations (n=56) defined as unique dates regardless of whether one or both breasts were involved.

Core Gel Study of the Safety and Effectiveness of the Mentor Round Gel-Filled Mammary Prosthesis
in Patients Who Are Undergoing Primary Breast Augmentation, Primary Breast Reconstruction or Revision

Table 9.2

REOPERATIVE REPORT. PRIMARY REASON FOR REOPERATION - FDA Item 11
AUGMENTATION PATIENTS

Time Period: 0 - 12 Months

Primary Reason for Reoperation	No. of Reoperation n(%)
RECURRENT BREAST CANCER	0 (0.0)
STAGED RECONSTRUCTION AND LEFT MASS, CHEST WALL	0 (0.0)
SUTURE REACTION	1 (1.8)
SYMMASTIA	0 (0.0)
TEAR IN CAPSULE	1 (1.8)
TIGHT BUNILLI SUTURE	0 (0.0)
MISSING	0 (0.0)

Note 1: Excludes planned second stage surgeries and reoperations for which the only reason for reoperation was staged reconstruction.
Note 2: Only the primary reason was to be recorded by the physician on a per-breast and per-operation basis. Patients having multiple operations, including operations on both breasts on the same date, will therefore be counted under multiple primary reasons. Consequently, percentages calculated may exceed 100%.
Note 3: Percentages are based upon the number of reoperations (n=56) defined as unique dates regardless of whether one or both breasts were involved.

Core Gel Study of the Safety and Effectiveness of the Mentor Round Gel-Filled Mammary Prosthesis
in Patients Who Are Undergoing Primary Breast Augmentation, Primary Breast Reconstruction or Revision

Table 9.2

REOPERATIVE REPORT: PRIMARY REASON FOR REOPERATION - FDA Item 11
AUGMENTATION PATIENTS

Time Period: 0 - 24 Months

Primary Reason for Reoperation	No. of Reoperation n(%)
ASYMMETRY	5 (6.0)
BREAST MASS	3 (3.6)
BREAST PAIN	2 (2.4)
CAPSULAR CONTRACTURE III/IV	36 (43.4)
DELAYED WOUND HEALING	1 (1.2)
EXTRUSION	1 (1.2)
HEMATOMA	11 (13.3)
HYPERTROPHIC SCARRING	12 (14.5)
IMPLANT MALPOSITION/DISPLACEMENT	3 (3.6)
INFECTION	3 (3.6)
IRRITATION/INFLAMMATION	0 (0.0)
NIPPLE RELATED (UNPLANNED)	0 (0.0)
PATIENT REQUEST	26 (31.3)
PTOSIS	2 (2.4)
SEROMA	1 (1.2)
WRINKLING	3 (3.6)
OTHER	3 (3.6)
BREAST / SKIN LESIONS	0 (0.0)
EXTRA SKIN BUMP	0 (0.0)
FALSE POSITIVE MRI FOR RUPTURE	1 (1.2)
GRANULOMA	0 (0.0)
LACK OF PROJECTION	0 (0.0)

Program Name: Q:\MENTOR\COREGEL\3YEAR\TABLES\T09_2.SAS Creation Date, Time: 03JAN05 14:21

Note 1: Excludes planned second stage surgeries and reoperations for which the only reason for reoperation was staged reconstruction.
Note 2: Only the primary reason was to be recorded by the physician on a per-breast and per-operation basis. Patients having multiple operations, including operations on both breasts on the same date, will therefore be counted under multiple primary reasons. Consequently, percentages calculated may exceed 100%.
Note 3: Percentages are based upon the number of reoperations (n=83) defined as unique dates regardless of whether one or both breasts were involved.

Core Gel Study of the Safety and Effectiveness of the Mentor Round Gel-Filled Mammary Prosthesis
in Patients Who Are Undergoing Primary Breast Augmentation, Primary Breast Reconstruction or Revision

Table 9.2

REOPERATIVE REPORT: PRIMARY REASON FOR REOPERATION - FDA Item 11
AUGMENTATION PATIENTS

Time Period: 0 - 24 Months

Primary Reason for Reoperation	No. of Reoperation n(%)
MUSCLE SPASM	0 (0.0)
PATIENT DISSATISFIED WITH APPEARANCE	0 (0.0)
POCKET TEAR	0 (0.0)
RECURRENT BREAST CANCER	0 (0.0)
STAGED RECONSTRUCTION AND LEFT MASS, CHEST WALL	0 (0.0)
SUTURE REACTION	1 (1.2)
SYMMASTIA	0 (0.0)
TEAR IN CAPSULE	1 (1.2)
TIGHT BUNILLI SUTURE	0 (0.0)
MISSING	0 (0.0)

Note 1: Excludes planned second stage surgeries and reoperations for which the only reason for reoperation was staged reconstruction.
Note 2: Only the primary reason was to be recorded by the physician on a per-breast and per-operation basis. Patients having multiple operations, including operations on both breasts on the same date, will therefore be counted under multiple primary reasons. Consequently, percentages calculated may exceed 100%.
Note 3: Percentages are based upon the number of reoperations (n=83) defined as unique dates regardless of whether one or both breasts were involved.

Core Gel Study of the Safety and Effectiveness of the Mentor Round Gel-Filled Mammary Prosthesis
in Patients Who Are Undergoing Primary Breast Augmentation, Primary Breast Reconstruction or Revision

Table 9.2

REOPERATIVE REPORT: PRIMARY REASON FOR REOPERATION - FDA Item 11
AUGMENTATION PATIENTS

Time Period: 0 - 36 Months

Primary Reason for Reoperation	No. of Reoperation n(%)
ASYMMETRY	5 (5.1)
BREAST MASS	4 (4.1)
BREAST PAIN	2 (2.0)
CAPSULAR CONTRACTURE III/IV	43 (43.9)
DELAYED WOUND HEALING	1 (1.0)
EXTRUSION	1 (1.0)
HEMATOMA	11 (11.2)
HYPERTROPHIC SCARRING	15 (15.3)
IMPLANT MALPOSITION/DISPLACEMENT	3 (3.1)
INFECTION	3 (3.1)
IRRITATION/INFLAMMATION	0 (0.0)
NECROSIS	2 (2.0)
NIPPLE RELATED (UNPLANNED)	0 (0.0)
PATIENT REQUEST	31 (31.6)
PTOSIS	5 (5.1)
SEROMA	1 (1.0)
WRINKLING	3 (3.1)
OTHER	4 (4.1)
ABNORMAL MAMMOGRAM	0 (0.0)
BREAST / SKIN LESIONS	0 (0.0)
EXTRA SKIN BUMP	0 (0.0)
FALSE POSITIVE MRI FOR RUPTURE	1 (1.0)

Program Name. Q:\MENTOR\COREGEL\3YEAR\TABLES\T09_2.SAS Creation Date, Time: 03JAN05 14:21

Note 1: Excludes planned second stage surgeries and reoperations for which the only reason for reoperation was staged reconstruction.
Note 2: Only the primary reason was to be recorded by the physician on a per-breast and per-operation basis. Patients having multiple operations, including operations on both breasts on the same date, will therefore be counted under multiple primary reasons. Consequently, percentages calculated may exceed 100%.
Note 3: Percentages are based upon the number of reoperations (n=98) defined as unique dates regardless of whether one or both breasts were involved.

Core Gel Study of the Safety and Effectiveness of the Mentor Round Gel-Filled Mammary Prosthesis
in Patients Who Are Undergoing Primary Breast Augmentation, Primary Breast Reconstruction or Revision

Table 9.2

REOPERATIVE REPORT. PRIMARY REASON FOR REOPERATION - FDA Item 11
AUGMENTATION PATIENTS

Time Period: 0 - 36 Months

Primary Reason for Reoperation	No. of Reoperation n(%)
GRANULOMA	0 (0.0)
LACK OF PROJECTION	0 (0.0)
MUSCLE SPASM	0 (0.0)
PATIENT DISSATISFIED WITH APPEARANCE	0 (0.0)
POCKET TEAR	0 (0.0)
RECURRENT BREAST CANCER	0 (0.0)
RIGHT EXPLANTED SO LEFT DONE ALSO	1 (1.0)
STAGED RECONSTRUCTION AND LEFT MASS, CHEST WALL	0 (0.0)
SUSPECTED RUPTURE	0 (0.0)
SUTURE REACTION	1 (1.0)
SYMMASTIA	0 (0.0)
TEAR IN CAPSULE	1 (1.0)
TIGHT BUNILLI SUTURE	0 (0.0)
TOO LARGE	0 (0.0)
MISSING	0 (0.0)

Note 1: Excludes planned second stage surgeries and reoperations for which the only reason for reoperation was staged reconstruction.
Note 2: Only the primary reason was to be recorded by the physician on a per-breast and per-operation basis. Patients having multiple operations, including operations on both breasts on the same date, will therefore be counted under multiple primary reasons. Consequently, percentages calculated may exceed 100%.
Note 3: Percentages are based upon the number of reoperations (n=98) defined as unique dates regardless of whether one or both breasts were involved.

Core Gel Study of the Safety and Effectiveness of the Mentor Round Gel-Filled Mammary Prosthesis
in Patients Who Are Undergoing Primary Breast Augmentation, Primary Breast Reconstruction or Revision

Table 9.2

REOPERATIVE REPORT: PRIMARY REASON FOR REOPERATION - FDA Item 11
RECONSTRUCTION PATIENTS

Time Period: 0 - 12 Months

Primary Reason for Reoperation	No. of Reoperation n(%)
ASYMMETRY	15 (27.3)
BREAST MASS	6 (10.9)
BREAST PAIN	1 (1.8)
CAPSULAR CONTRACTURE III/IV	6 (10.9)
DELAYED WOUND HEALING	0 (0.0)
EXTRUSION	2 (3.6)
HEMATOMA	1 (1.8)
HYPERTROPHIC SCARRING	0 (0.0)
IMPLANT MALPOSITION/DISPLACEMENT	7 (12.7)
INFECTION	4 (7.3)
IRRITATION/INFLAMMATION	0 (0.0)
NIPPLE RELATED (UNPLANNED)	2 (3.6)
PATIENT REQUEST	10 (18.2)
PTOSIS	1 (1.8)
SEROMA	1 (1.8)
WRINKLING	0 (0.0)
OTHER	8 (14.5)
BREAST / SKIN LESIONS	1 (1.8)
EXTRA SKIN BUMP	1 (1.8)
GRANULOMA	0 (0.0)
MUSCLE SPASM	1 (1.8)
POCKET TEAR	0 (0.0)

Program Name. Q:\MENTOR\COREGEL\3YEAR\TABLES\T09_2.SAS Creation Date, Time: 03JAN05 14:21

Note 1: Excludes planned second stage surgeries and reoperations for which the only reason for reoperation was staged reconstruction.
Note 2: Only the primary reason was to be recorded by the physician on a per-breast and per-operation basis. Patients having multiple operations, including operations on both breasts on the same date, will therefore be counted under multiple primary reasons. Consequently, percentages calculated may exceed 100%.
Note 3: Percentages are based upon the number of reoperations (n=55) defined as unique dates regardless of whether one or both breasts were involved.

Core Gel Study of the Safety and Effectiveness of the Mentor Round Gel-Filled Mammary Prosthesis
in Patients Who Are Undergoing Primary Breast Augmentation, Primary Breast Reconstruction or Revision

Table 9.2

REOPERATIVE REPORT: PRIMARY REASON FOR REOPERATION - FDA Item 11
RECONSTRUCTION PATIENTS

Time Period: 0 - 12 Months

Primary Reason for Reoperation	No. of Reoperation n(%)
RECURRENT BREAST CANCER	2 (3.6)
STAGED RECONSTRUCTION AND LEFT MASS, CHEST WALL	2 (3.6)
SUTURE REACTION	0 (0.0)
SYMMASTIA	0 (0.0)
TEAR IN CAPSULE	0 (0.0)
TIGHT BUNILLI SUTURE	1 (1.8)
MISSING	2 (3.6)

Note 1: Excludes planned second stage surgeries and reoperations for which the only reason for reoperation was staged reconstruction.
Note 2: Only the primary reason was to be recorded by the physician on a per-breast and per-operation basis. Patients having multiple operations, including operations on both breasts on the same date, will therefore be counted under multiple primary reasons. Consequently, percentages calculated may exceed 100%.
Note 3: Percentages are based upon the number of reoperations (n=55) defined as unique dates regardless of whether one or both breasts were involved.

Core Gel Study of the Safety and Effectiveness of the Mentor Round Gel-Filled Mammary Prosthesis
in Patients Who Are Undergoing Primary Breast Augmentation, Primary Breast Reconstruction or Revision

Table 9.2

REOPERATIVE REPORT: PRIMARY REASON FOR REOPERATION - FDA Item 11
RECONSTRUCTION PATIENTS

Time Period: 0 - 24 Months

Primary Reason for Reoperation	No. of Reoperation n(%)
ASYMMETRY	20 (27.4)
BREAST MASS	8 (11.0)
BREAST PAIN	1 (1.4)
CAPSULAR CONTRACTURE III/IV	10 (13.7)
DELAYED WOUND HEALING	0 (0.0)
EXTRUSION	2 (2.7)
HEMATOMA	1 (1.4)
HYPERTROPHIC SCARRING	3 (4.1)
IMPLANT MALPOSITION/DISPLACEMENT	11 (15.1)
INFECTION	4 (5.5)
IRRITATION/INFLAMMATION	0 (0.0)
NIPPLE RELATED (UNPLANNED)	2 (2.7)
PATIENT REQUEST	11 (15.1)
PTOSIS	3 (4.1)
SEROMA	1 (1.4)
WRINKLING	0 (0.0)
OTHER	9 (12.3)
BREAST / SKIN LESIONS	1 (1.4)
EXTRA SKIN BUMP	1 (1.4)
FALSE POSITIVE MRI FOR RUPTURE	0 (0.0)
GRANULOMA	0 (0.0)
LACK OF PROJECTION	1 (1.4)

Program Name: Q:\MENTOR\COREGEL\3YEAR\TABLES\T09_2.SAS Creation Date, Time: 03JAN05 14:21

Note 1: Excludes planned second stage surgeries and reoperations for which the only reason for reoperation was staged reconstruction.
Note 2: Only the primary reason was to be recorded by the physician on a per-breast and per-operation basis. Patients having multiple operations, including operations on both breasts on the same date, will therefore be counted under multiple primary reasons. Consequently, percentages calculated may exceed 100%.
Note 3: Percentages are based upon the number of reoperations (n=73) defined as unique dates regardless of whether one or both breasts were involved.

Core Gel Study of the Safety and Effectiveness of the Mentor Round Gel-Filled Mammary Prosthesis
in Patients Who Are Undergoing Primary Breast Augmentation, Primary Breast Reconstruction or Revision

Table 9.2

REOPERATIVE REPORT: PRIMARY REASON FOR REOPERATION - FDA Item 11
RECONSTRUCTION PATIENTS

Time Period: 0 - 24 Months

Primary Reason for Reoperation	No. of Reoperation n(%)
MUSCLE SPASM	1 (1.4)
PATIENT DISSATISFIED WITH APPEARANCE	0 (0.0)
POCKET TEAR	0 (0.0)
RECURRENT BREAST CANCER	2 (2.7)
STAGED RECONSTRUCTION AND LEFT MASS, CHEST WALL	2 (2.7)
SUTURE REACTION	0 (0.0)
SYMMASTIA	0 (0.0)
TEAR IN CAPSULE	0 (0.0)
TIGHT BUNILLI SUTURE	1 (1.4)
MISSING	2 (2.7)

Note 1: Excludes planned second stage surgeries and reoperations for which the only reason for reoperation was staged reconstruction.
Note 2: Only the primary reason was to be recorded by the physician on a per-breast and per-operation basis. Patients having multiple operations, including operations on both breasts on the same date, will therefore be counted under multiple primary reasons. Consequently, percentages calculated may exceed 100%.
Note 3: Percentages are based upon the number of reoperations (n=73) defined as unique dates regardless of whether one or both breasts were involved.

Core Gel Study of the Safety and Effectiveness of the Mentor Round Gel-Filled Mammary Prosthesis
in Patients Who Are Undergoing Primary Breast Augmentation, Primary Breast Reconstruction or Revision

Table 9.2

REOPERATIVE REPORT: PRIMARY REASON FOR REOPERATION - FDA Item 11
RECONSTRUCTION PATIENTS

Time Period: 0 - 36 Months

Primary Reason for Reoperation	No. of Reoperation n(%)
ASYMMETRY	20 (25.6)
BREAST MASS	9 (11.5)
BREAST PAIN	1 (1.3)
CAPSULAR CONTRACTURE III/IV	10 (12.8)
DELAYED WOUND HEALING	0 (0.0)
EXTRUSION	2 (2.6)
HEMATOMA	2 (2.6)
HYPERTROPHIC SCARRING	3 (3.8)
IMPLANT MALPOSITION/DISPLACEMENT	11 (14.1)
INFECTION	4 (5.1)
IRRITATION/INFLAMMATION	0 (0.0)
NECROSIS	0 (0.0)
NIPPLE RELATED (UNPLANNED)	2 (2.6)
PATIENT REQUEST	13 (16.7)
PTOSIS	4 (5.1)
SEROMA	1 (1.3)
WRINKLING	0 (0.0)
OTHER	11 (14.1)
ABNORMAL MAMMOGRAM	0 (0.0)
BREAST / SKIN LESIONS	1 (1.3)
EXTRA SKIN BUMP	1 (1.3)
FALSE POSITIVE MRI FOR RUPTURE	0 (0.0)

Program Name: Q:\MENTOR\COREGEL\3YEAR\TABLES\T09_2.SAS

Creation Date, Time: 03JAN05 14:21

Note 1: Excludes planned second stage surgeries and reoperations for which the only reason for reoperation was staged reconstruction.
Note 2: Only the primary reason was to be recorded by the physician on a per-breast and per-operation basis. Patients having multiple operations, including operations on both breasts on the same date, will therefore be counted under multiple primary reasons. Consequently, percentages calculated may exceed 100%.
Note 3: Percentages are based upon the number of reoperations (n=78) defined as unique dates regardless of whether one or both breasts were involved.

Core Gel Study of the Safety and Effectiveness of the Mentor Round Gel-Filled Mammary Prosthesis
in Patients Who Are Undergoing Primary Breast Augmentation, Primary Breast Reconstruction or Revision

Table 9.2

REOPERATIVE REPORT: PRIMARY REASON FOR REOPERATION - FDA Item 11
RECONSTRUCTION PATIENTS

Time Period: 0 - 36 Months

Primary Reason for Reoperation	No. of Reoperation n(%)
GRANULOMA	0 (0.0)
LACK OF PROJECTION	1 (1.3)
MUSCLE SPASM	1 (1.3)
PATIENT DISSATISFIED WITH APPEARANCE	0 (0.0)
POCKET TEAR	0 (0.0)
RECURRENT BREAST CANCER	2 (2.6)
RIGHT EXPLANTED SO LEFT DONE ALSO	0 (0.0)
STAGED RECONSTRUCTION AND LEFT MASS, CHEST WALL	2 (2.6)
SUSPECTED RUPTURE	0 (0.0)
SUTURE REACTION	0 (0.0)
SYMMASTIA	0 (0.0)
TEAR IN CAPSULE	0 (0.0)
TIGHT BUNILLI SUTURE	1 (1.3)
TOO LARGE	2 (2.6)
MISSING	2 (2.6)

Note 1: Excludes planned second stage surgeries and reoperations for which the only reason for reoperation was staged reconstruction.
Note 2: Only the primary reason was to be recorded by the physician on a per-breast and per-operation basis. Patients having multiple operations, including operations on both breasts on the same date, will therefore be counted under multiple primary reasons. Consequently, percentages calculated may exceed 100%.
Note 3: Percentages are based upon the number of reoperations (n=78) defined as unique dates regardless of whether one or both breasts were involved.

Core Gel Study of the Safety and Effectiveness of the Mentor Round Gel-Filled Mammary Prosthesis
in Patients Who Are Undergoing Primary Breast Augmentation, Primary Breast Reconstruction or Revision

Table 9.2

REOPERATIVE REPORT: PRIMARY REASON FOR REOPERATION - FDA Item 11
REVISION PATIENTS

Time Period: 0 - 12 Months

Primary Reason for Reoperation	No. of Reoperation n(%)
ASYMMETRY	1 (2.2)
BREAST MASS	4 (8.9)
BREAST PAIN	0 (0.0)
CAPSULAR CONTRACTURE III/IV	21 (46.7)
DELAYED WOUND HEALING	4 (8.9)
EXTRUSION	3 (6.7)
HEMATOMA	4 (8.9)
HYPERTROPHIC SCARRING	2 (4.4)
IMPLANT MALPOSITION/DISPLACEMENT	2 (4.4)
INFECTION	0 (0.0)
IRRITATION/INFLAMMATION	1 (2.2)
NIPPLE RELATED (UNPLANNED)	2 (4.4)
PATIENT REQUEST	5 (11.1)
PTOSIS	0 (0.0)
SEROMA	1 (2.2)
WRINKLING	2 (4.4)
OTHER	9 (20.0)
BREAST / SKIN LESIONS	2 (4.4)
EXTRA SKIN BUMP	0 (0.0)
GRANULOMA	1 (2.2)
MUSCLE SPASM	0 (0.0)
POCKET TEAR	1 (2.2)

Program Name: Q:\MENTOR\COREGEL\3YEAR\TABLES\T09_2.SAS

Creation Date, Time: 03JAN05 14:21

Note 1: Excludes planned second stage surgeries and reoperations for which the only reason for reoperation was staged reconstruction.
Note 2: Only the primary reason was to be recorded by the physician on a per-breast and per-operation basis. Patients having multiple operations, including operations on both breasts on the same date, will therefore be counted under multiple primary reasons. Consequently, percentages calculated may exceed 100%.
Note 3: Percentages are based upon the number of reoperations (n=45) defined as unique dates regardless of whether one or both breasts were involved.

Core Gel Study of the Safety and Effectiveness of the Mentor Round Gel-Filled Mammary Prosthesis
in Patients Who Are Undergoing Primary Breast Augmentation, Primary Breast Reconstruction or Revision

Table 9.2

REOPERATIVE REPORT: PRIMARY REASON FOR REOPERATION - FDA Item 11
REVISION PATIENTS

Time Period: 0 - 12 Months

Primary Reason for Reoperation	No. of Reoperation n(%)
RECURRENT BREAST CANCER	1 (2.2)
STAGED RECONSTRUCTION AND LEFT MASS, CHEST WALL	0 (0.0)
SUTURE REACTION	0 (0.0)
SYMMASTIA	4 (8.9)
TEAR IN CAPSULE	0 (0.0)
TIGHT BUNILLI SUTURE	0 (0.0)
MISSING	0 (0.0)

Note 1: Excludes planned second stage surgeries and reoperations for which the only reason for reoperation was staged reconstruction.
Note 2: Only the primary reason was to be recorded by the physician on a per-breast and per-operation basis. Patients having multiple operations, including operations on both breasts on the same date, will therefore be counted under multiple primary reasons. Consequently, percentages calculated may exceed 100%.
Note 3: Percentages are based upon the number of reoperations (n=45) defined as unique dates regardless of whether one or both breasts were involved.

Core Gel Study of the Safety and Effectiveness of the Mentor Round Gel-Filled Mammary Prosthesis
in Patients Who Are Undergoing Primary Breast Augmentation, Primary Breast Reconstruction or Revision

Table 9.2

REOPERATIVE REPORT: PRIMARY REASON FOR REOPERATION - FDA Item 11
REVISION PATIENTS

Time Period: 0 - 24 Months

Primary Reason for Reoperation	No. of Reoperation n(%)
ASYMMETRY	3 (4.8)
BREAST MASS	5 (8.1)
BREAST PAIN	0 (0.0)
CAPSULAR CONTRACTURE III/IV	24 (38.7)
DELAYED WOUND HEALING	4 (6.5)
EXTRUSION	3 (4.8)
HEMATOMA	5 (8.1)
HYPERTROPHIC SCARRING	4 (6.5)
IMPLANT MALPOSITION/DISPLACEMENT	3 (4.8)
INFECTION	1 (1.6)
IRRITATION/INFLAMMATION	1 (1.6)
NIPPLE RELATED (UNPLANNED)	2 (3.2)
PATIENT REQUEST	12 (19.4)
PTOSIS	2 (3.2)
SEROMA	1 (1.6)
WRINKLING	4 (6.5)
OTHER	12 (19.4)
BREAST / SKIN LESIONS	3 (4.8)
EXTRA SKIN BUMP	0 (0.0)
FALSE POSITIVE MRI FOR RUPTURE	0 (0.0)
GRANULOMA	1 (1.6)
LACK OF PROJECTION	0 (0.0)

Program Name. Q.\MENTOR\COREGEL\3YEAR\TABLES\T09_2.SAS Creation Date, Time: 03JAN05 14:21

Note 1: Excludes planned second stage surgeries and reoperations for which the only reason for reoperation was staged reconstruction.
Note 2: Only the primary reason was to be recorded by the physician on a per-breast and per-operation basis. Patients having multiple operations, including operations on both breasts on the same date, will therefore be counted under multiple primary reasons. Consequently, percentages calculated may exceed 100%.
Note 3: Percentages are based upon the number of reoperations (n=62) defined as unique dates regardless of whether one or both breasts were involved.

Core Gel Study of the Safety and Effectiveness of the Mentor Round Gel-Filled Mammary Prosthesis
in Patients Who Are Undergoing Primary Breast Augmentation, Primary Breast Reconstruction or Revision

Table 9.2

REOPERATIVE REPORT: PRIMARY REASON FOR REOPERATION - FDA Item 11
REVISION PATIENTS

Time Period: 0 - 24 Months

Primary Reason for Reoperation	No. of Reoperation n(%)
MUSCLE SPASM	0 (0.0)
PATIENT DISSATISFIED WITH APPEARANCE	2 (3.2)
POCKET TEAR	1 (1.6)
RECURRENT BREAST CANCER	1 (1.6)
STAGED RECONSTRUCTION AND LEFT MASS, CHEST WALL	0 (0.0)
SUTURE REACTION	0 (0.0)
SYMMASTIA	4 (6.5)
TEAR IN CAPSULE	0 (0.0)
TIGHT BUNILLI SUTURE	0 (0.0)
MISSING	0 (0.0)

Note 1. Excludes planned second stage surgeries and reoperations for which the only reason for reoperation was staged reconstruction.
Note 2: Only the primary reason was to be recorded by the physician on a per-breast and per-operation basis. Patients having multiple operations, including operations on both breasts on the same date, will therefore be counted under multiple primary reasons. Consequently, percentages calculated may exceed 100%.
Note 3: Percentages are based upon the number of reoperations (n=62) defined as unique dates regardless of whether one or both breasts were involved.

Core Gel Study of the Safety and Effectiveness of the Mentor Round Gel-Filled Mammary Prosthesis
in Patients Who Are Undergoing Primary Breast Augmentation, Primary Breast Reconstruction or Revision

Table 9.2

REOPERATIVE REPORT: PRIMARY REASON FOR REOPERATION - FDA Item 11
REVISION PATIENTS

Time Period: 0 - 36 Months

Primary Reason for Reoperation	No. of Reoperation n(%)
ASYMMETRY	3 (4.2)
BREAST MASS	6 (8.5)
BREAST PAIN	0 (0.0)
CAPSULAR CONTRACTURE III/IV	28 (39.4)
DELAYED WOUND HEALING	4 (5.6)
EXTRUSION	3 (4.2)
HEMATOMA	5 (7.0)
HYPERTROPHIC SCARRING	5 (7.0)
IMPLANT MALPOSITION/DISPLACEMENT	3 (4.2)
INFECTION	1 (1.4)
IRRITATION/INFLAMMATION	1 (1.4)
NECROSIS	0 (0.0)
NIPPLE RELATED (UNPLANNED)	2 (2.8)
PATIENT REQUEST	14 (19.7)
PTOSIS	4 (5.6)
SEROMA	1 (1 4)
WRINKLING	4 (5.6)
OTHER	15 (21 1)
ABNORMAL MAMMOGRAM	1 (1.4)
BREAST / SKIN LESIONS	3 (4.2)
EXTRA SKIN BUMP	0 (0.0)
FALSE POSITIVE MRI FOR RUPTURE	1 (1.4)

Program Name: Q:\MENTOR\COREGEL\3YEAR\TABLES\T09_2.SAS

Creation Date, Time: 03JAN05 14:21

Note 1: Excludes planned second stage surgeries and reoperations for which the only reason for reoperation was staged reconstruction.
Note 2: Only the primary reason was to be recorded by the physician on a per-breast and per-operation basis. Patients having multiple operations, including operations on both breasts on the same date, will therefore be counted under multiple primary reasons. Consequently, percentages calculated may exceed 100%.
Note 3: Percentages are based upon the number of reoperations (n=71) defined as unique dates regardless of whether one or both breasts were involved.

Core Gel Study of the Safety and Effectiveness of the Mentor Round Gel-Filled Mammary Prosthesis
in Patients Who Are Undergoing Primary Breast Augmentation, Primary Breast Reconstruction or Revision

Table 9 2

REOPERATIVE REPORT: PRIMARY REASON FOR REOPERATION - FDA Item 11
REVISION PATIENTS

Time Period: 0 - 36 Months

Primary Reason for Reoperation	No. of Reoperation n(%)
GRANULOMA	1 (1.4)
LACK OF PROJECTION	0 (0.0)
MUSCLE SPASM	0 (0.0)
PATIENT DISSATISFIED WITH APPEARANCE	2 (2.8)
POCKET TEAR	1 (1.4)
RECURRENT BREAST CANCER	1 (1.4)
RIGHT EXPLANTED SO LEFT DONE ALSO	0 (0.0)
STAGED RECONSTRUCTION AND LEFT MASS, CHEST WALL	0 (0.0)
SUSPECTED RUPTURE	1 (1.4)
SUTURE REACTION	0 (0.0)
SYMMASTIA	4 (5.6)
TEAR IN CAPSULE	0 (0.0)
TIGHT BUNILLI SUTURE	0 (0.0)
TOO LARGE	0 (0.0)
MISSING	1 (1.4)

Note 1: Excludes planned second stage surgeries and reoperations for which the only reason for reoperation was staged reconstruction.
Note 2: Only the primary reason was to be recorded by the physician on a per-breast and per-operation basis. Patients having multiple operations, including operations on both breasts on the same date, will therefore be counted under multiple primary reasons. Consequently, percentages calculated may exceed 100%.
Note 3: Percentages are based upon the number of reoperations (n=71) defined as unique dates regardless of whether one or both breasts were involved.

Core Gel Study of the Safety and Effectiveness of the Mentor Round Gel-Filled Mammary Prosthesis
in Patients Who Are Undergoing Primary Breast Augmentation, Primary Breast Reconstruction or Revision

Table 9.2

REOPERATIVE REPORT: PRIMARY REASON FOR REOPERATION - FDA Item 11
OVERALL PATIENTS

Time Period: 0 - 12 Months

Primary Reason for Reoperation	No. of Reoperation n(%)
ASYMMETRY	21 (13.5)
BREAST MASS	11 (7.1)
BREAST PAIN	1 (0.6)
CAPSULAR CONTRACTURE III/IV	49 (31.4)
DELAYED WOUND HEALING	5 (3.2)
EXTRUSION	6 (3.8)
HEMATOMA	15 (9.6)
HYPERTROPHIC SCARRING	6 (3.8)
IMPLANT MALPOSITION/DISPLACEMENT	10 (6.4)
INFECTION	7 (4.5)
IRRITATION/INFLAMMATION	1 (0.6)
NIPPLE RELATED (UNPLANNED)	4 (2.6)
PATIENT REQUEST	34 (21.8)
PTOSIS	3 (1.9)
SEROMA	3 (1.9)
WRINKLING	3 (1.9)
OTHER	19 (12.2)
BREAST / SKIN LESIONS	3 (1.9)
EXTRA SKIN BUMP	1 (0.6)
GRANULOMA	1 (0.6)
MUSCLE SPASM	1 (0.6)
POCKET TEAR	1 (0.6)

Program Name: Q.\MENTOR\COREGEL\3YEAR\TABLES\T09_2.SAS

Creation Date, Time: 03JAN05 14:21

Note 1: Excludes planned second stage surgeries and reoperations for which the only reason for reoperation was staged reconstruction.
Note 2: Only the primary reason was to be recorded by the physician on a per-breast and per-operation basis. Patients having multiple operations, including operations on both breasts on the same date, will therefore be counted under multiple primary reasons. Consequently, percentages calculated may exceed 100%.
Note 3. Percentages are based upon the number of reoperations (n=156) defined as unique dates regardless of whether one or both breasts were involved.

Core Gel Study of the Safety and Effectiveness of the Mentor Round Gel-Filled Mammary Prosthesis
in Patients Who Are Undergoing Primary Breast Augmentation, Primary Breast Reconstruction or Revision

Table 9.2

REOPERATIVE REPORT: PRIMARY REASON FOR REOPERATION - FDA Item 11
OVERALL PATIENTS

Time Period: 0 - 12 Months

Primary Reason for Reoperation	No. of Reoperation n(%)
RECURRENT BREAST CANCER	3 (1.9)
STAGED RECONSTRUCTION AND LEFT MASS, CHEST WALL	2 (1.3)
SUTURE REACTION	1 (0.6)
SYMMASTIA	4 (2.6)
TEAR IN CAPSULE	1 (0.6)
TIGHT BUNILLI SUTURE	1 (0.6)
MISSING	2 (1.3)

Note 1: Excludes planned second stage surgeries and reoperations for which the only reason for reoperation was staged reconstruction.
Note 2: Only the primary reason was to be recorded by the physician on a per-breast and per-operation basis. Patients having multiple operations, including operations on both breasts on the same date, will therefore be counted under multiple primary reasons. Consequently, percentages calculated may exceed 100%.
Note 3: Percentages are based upon the number of reoperations (n=156) defined as unique dates regardless of whether one or both breasts were involved.

Core Gel Study of the Safety and Effectiveness of the Mentor Round Gel-Filled Mammary Prosthesis
in Patients Who Are Undergoing Primary Breast Augmentation, Primary Breast Reconstruction or Revision

Table 9.2

REOPERATIVE REPORT: PRIMARY REASON FOR REOPERATION - FDA Item 11
OVERALL PATIENTS

Time Period: 0 - 24 Months

Primary Reason for Reoperation	No. of Reoperation n(%)
ASYMMETRY	28 (12.8)
BREAST MASS	16 (7.3)
BREAST PAIN	3 (1.4)
CAPSULAR CONTRACTURE III/IV	70 (32.1)
DELAYED WOUND HEALING	5 (2.3)
EXTRUSION	6 (2.8)
HEMATOMA	17 (7.8)
HYPERTROPHIC SCARRING	19 (8.7)
IMPLANT MALPOSITION/DISPLACEMENT	17 (7.8)
INFECTION	8 (3.7)
IRRITATION/INFLAMMATION	1 (0.5)
NIPPLE RELATED (UNPLANNED)	4 (1.8)
PATIENT REQUEST	49 (22.5)
PTOSIS	7 (3.2)
SEROMA	3 (1.4)
WRINKLING	7 (3.2)
OTHER	24 (11.0)
BREAST / SKIN LESIONS	4 (1.8)
EXTRA SKIN BUMP	1 (0.5)
FALSE POSITIVE MRI FOR RUPTURE	1 (0.5)
GRANULOMA	1 (0.5)
LACK OF PROJECTION	1 (0.5)

Program Name. Q:\MENTOR\COREGEL\3YEAR\TABLES\T09_2.SAS

Creation Date, Time: 03JAN05 14:21

Note 1: Excludes planned second stage surgeries and reoperations for which the only reason for reoperation was staged reconstruction.
Note 2: Only the primary reason was to be recorded by the physician on a per-breast and per-operation basis. Patients having multiple operations, including operations on both breasts on the same date, will therefore be counted under multiple primary reasons. Consequently, percentages calculated may exceed 100%.
Note 3: Percentages are based upon the number of reoperations (n=218) defined as unique dates regardless of whether one or both breasts were involved.

Core Gel Study of the Safety and Effectiveness of the Mentor Round Gel-Filled Mammary Prosthesis
in Patients Who Are Undergoing Primary Breast Augmentation, Primary Breast Reconstruction or Revision

Table 9.2

REOPERATIVE REPORT: PRIMARY REASON FOR REOPERATION - FDA Item 11
OVERALL PATIENTS

Time Period: 0 - 24 Months

Primary Reason for Reoperation	No. of Reoperation n(%)
MUSCLE SPASM	1 (0.5)
PATIENT DISSATISFIED WITH APPEARANCE	2 (0.9)
POCKET TEAR	1 (0.5)
RECURRENT BREAST CANCER	3 (1.4)
STAGED RECONSTRUCTION AND LEFT MASS, CHEST WALL	2 (0.9)
SUTURE REACTION	1 (0.5)
SYMMASTIA	4 (1.8)
TEAR IN CAPSULE	1 (0.5)
TIGHT BUNILLI SUTURE	1 (0.5)
MISSING	2 (0.9)

Note 1: Excludes planned second stage surgeries and reoperations for which the only reason for reoperation was staged reconstruction.
Note 2: Only the primary reason was to be recorded by the physician on a per-breast and per-operation basis. Patients having multiple operations, including operations on both breasts on the same date, will therefore be counted under multiple primary reasons. Consequently, percentages calculated may exceed 100%.
Note 3: Percentages are based upon the number of reoperations (n=218) defined as unique dates regardless of whether one or both breasts were involved.

Core Gel Study of the Safety and Effectiveness of the Mentor Round Gel-Filled Mammary Prosthesis
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Table 9.2

REOPERATIVE REPORT: PRIMARY REASON FOR REOPERATION - FDA Item 11
OVERALL PATIENTS

Time Period: 0 - 36 Months

Primary Reason for Reoperation	No. of Reoperation n(%)
ASYMMETRY	28 (11.3)
BREAST MASS	19 (7.7)
BREAST PAIN	3 (1.2)
CAPSULAR CONTRACTURE III/IV	81 (32.8)
DELAYED WOUND HEALING	5 (2.0)
EXTRUSION	6 (2.4)
HEMATOMA	18 (7.3)
HYPERTROPHIC SCARRING	23 (9.3)
IMPLANT MALPOSITION/DISPLACEMENT	17 (6.9)
INFECTION	8 (3.2)
IRRITATION/INFLAMMATION	1 (0.4)
NECROSIS	2 (0.8)
NIPPLE RELATED (UNPLANNED)	4 (1.6)
PATIENT REQUEST	58 (23.5)
PTOSIS	13 (5.3)
SEROMA	3 (1.2)
WRINKLING	7 (2.8)
OTHER	30 (12.1)
ABNORMAL MAMMOGRAM	1 (0.4)
BREAST / SKIN LESIONS	4 (1.6)
EXTRA SKIN BUMP	1 (0.4)
FALSE POSITIVE MRI FOR RUPTURE	2 (0.8)

Program Name. Q:\MENTOR\COREGEL\3YEAR\TABLES\T09_2.SAS Creation Date, Time: 03JAN05 14:21

Note 1: Excludes planned second stage surgeries and reoperations for which the only reason for reoperation was staged reconstruction.
Note 2: Only the primary reason was to be recorded by the physician on a per-breast and per-operation basis. Patients having multiple operations, including operations on both breasts on the same date, will therefore be counted under multiple primary reasons. Consequently, percentages calculated may exceed 100%.
Note 3: Percentages are based upon the number of reoperations (n=247) defined as unique dates regardless of whether one or both breasts were involved.

Core Gel Study of the Safety and Effectiveness of the Mentor Round Gel-Filled Mammary Prosthesis
in Patients Who Are Undergoing Primary Breast Augmentation, Primary Breast Reconstruction or Revision

Table 9.2

REOPERATIVE REPORT: PRIMARY REASON FOR REOPERATION - FDA Item 11
OVERALL PATIENTS

Time Period: 0 - 36 Months

Primary Reason for Reoperation	No. of Reoperation n(%)
GRANULOMA	1 (0.4)
LACK OF PROJECTION	1 (0.4)
MUSCLE SPASM	1 (0.4)
PATIENT DISSATISFIED WITH APPEARANCE	2 (0.8)
POCKET TEAR	1 (0.4)
RECURRENT BREAST CANCER	3 (1.2)
RIGHT EXPLANTED SO LEFT DONE ALSO	1 (0.4)
STAGED RECONSTRUCTION AND LEFT MASS, CHEST WALL	2 (0.8)
SUSPECTED RUPTURE	1 (0.4)
SUTURE REACTION	1 (0.4)
SYMMASTIA	4 (1.6)
TEAR IN CAPSULE	1 (0.4)
TIGHT BUNILLI SUTURE	1 (0.4)
TOO LARGE	2 (0.8)
MISSING	3 (1.2)

Note 1: Excludes planned second stage surgeries and reoperations for which the only reason for reoperation was staged reconstruction.
Note 2: Only the primary reason was to be recorded by the physician on a per-breast and per-operation basis. Patients having multiple operations, including operations on both breasts on the same date, will therefore be counted under multiple primary reasons. Consequently, percentages calculated may exceed 100%.
Note 3: Percentages are based upon the number of reoperations (n=247) defined as unique dates regardless of whether one or both breasts were involved.